DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 1 2012

Re: Convenia
Docket No.: FDA-2009-E-0087
Previously 2004E-0040

Luçy X. Yang
Attorney for Applicant
Pfizer Inc.
7000 Portage Road
Kalamazoo, MI 49001

RE: Patent Term Extension for Pfizer Inc., U.S. Patent No. 6,020,329, Convenia, Request for Revision of Regulatory Review Period

Dear Ms. Yang:

This letter is in response to your letters dated June 27, 2011, and July 1, 2011, on behalf of Pfizer Inc. (Pfizer) for revision of the regulatory review period for Convenia (cefovecin sodium), U.S. Patent No. 6,020,329, filed by Pfizer under Title 35 United States Code (35 U.S.C.) 156 et seq.

In the April 29, 2011, issue of the *Federal Register* (76 FR 24034), the Food and Drug Administration (FDA) published its determination of this product's regulatory review period for purposes of patent term extension, as required under 35 U.S.C. 156(d)(2)(A). As described below, FDA reaffirms the determination of the regulatory review period as published.

I. Your Request

In the *Federal Register* notice, FDA determined that the date the investigational new animal drug application (INAD) became effective was July 17, 2000, and the date of submission of the new animal drug application (NADA) for Convenia was March 17, 2008. You believe these dates should be revised, and you request FDA reconsideration as follows:

(a) The effective date of the INAD should be January 21, 2000, instead of July 17, 2000.
(b) In FDA's letter dated November 16, 1999, FDA assigned Pfizer two INAD file numbers, INAD-10612 (dogs) and INAD-10613 (cats). You state that obtaining an INAD docket marks the beginning of the testing phase.
(c) FDA accepted the protocol entitled, "Acute Safety Toleration of UK-287,074 in Dogs" on January 21, 2000. You believe this acceptance indicated an exemption for the study to begin under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the Act).
(d) The initial date of submission of the NADA for Convenia was March 13, 2008, instead of March 17, 2008.

II. FDA Response

A. Regulatory Review Period

For purposes of patent term extension, a regulatory review period is the sum of two periods of time: a testing phase and an approval phase. As clarified in Title 21 Code of Federal Regulations (21 CFR) 60.22(d)(1), for animal drug products, the testing phase begins on the date a major health or environmental effects test is begun or the date on which the Agency acknowledges the filing of a notice of claimed investigational exemption (NCIE) for a new animal drug, whichever is earlier, and ends on the date a marketing application under section 512 of the Act is initially submitted to FDA. The approval phase begins on the date a marketing application under section 512 of the Act is initially submitted to FDA and ends on the date the application is approved (21 CFR 60.22(d)(2)). Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

B. What is the earliest effective date of the INADs for Convenia?

According to the initial patent term restoration application, Pfizer claimed that an exemption under section 512(j) of the Act became effective for Convenia on November 16, 1999, following submission of INAD nos. 10612 and 10613 on August 5, and August 6, 1999, respectively. In your revision request, you state that FDA assigned Pfizer two INAD numbers on November 16, 1999, and you believe that "typically, obtaining an INAD docket marks the beginning of the testing phase." Alternatively, you request that FDA consider January 21, 2000, the date of FDA's letter accepting the study protocol, as the effective date of the INAD.

21 CFR 60.24(c) provides that FDA must apply the provisions of 21 CFR 60.22 in considering the request for a revision of the regulatory review period determination. As noted above, 21 CFR 60.22(d) states that the effective date of the INAD is the date the Agency acknowledges the filing of the NCIE[1] or the date a major health or environmental effects test is begun for a new animal drug, whichever is earlier. You do not assert that any relevant test began before July 17, 2000; therefore, the only remaining question relates to the filing of the NCIE. Neither the November 16, 1999, letter assigning the INAD numbers, nor the January 21, 2000, protocol concurrence letter constituted an NCIE. We have confirmed with the Center for Veterinary Medicine (CVM) that July 17, 2000, was the date that the first NCIE was received from Pfizer for INAD 10612.

[1] According to the CVM Program Policy and Procedures Manual 1243.4065 (April 3, 2009), the requirements for establishing an INAD file are separate from the requirements for sponsors seeking an investigational exemption. The investigational exemption legally allows a sponsor to ship unapproved new animal drugs in interstate commerce for investigational use.

Therefore, we affirm our prior determination that the testing period started on July 17, 2000, the date that the first NCIE was received for the new animal drug from Pfizer.

C. What date was the NADA for Convenia initially submitted under section 512?

As noted above, the approval phase for new animal drug products begins on the date the new animal drug application is initially *submitted* under section 512 of the Act. According to FDA records, CVM received the NADA, when the application was initially submitted under section 512 of the Act, on March 17, 2008. The date you claim as the initially submitted date, March 13, 2008, is the correspondence letter date. For ease of reference in correspondence to identify specific documents from the applicant, FDA usually refers to the submission by its correspondence letter date. In the case of NADA 141-285, the correspondence letter date of the original submission was March 13, 2008, and the application was received for review by the Agency on March 17, 2008. FDA's use of this shorthand for ease of reference to specific documents does not mean that FDA concedes that this date represents the actual date of submission.

III. Conclusion

FDA received your timely request for reconsideration and revision of the determination of the regulatory review period on June 28, 2011, before the comment period had closed. As described above, FDA has carefully reviewed its records and the determination of the regulatory review period for Convenia (cefovecin sodium), U.S. Patent No. 6,020,329, filed by Pfizer under 35 U.S.C. 156 et seq., and published in the *Federal Register* of April 29, 2011. FDA affirms the determination of the regulatory review period as published. Consequently, the regulatory review period for Convenia as published in the April 29, 2011, *Federal Register* is correct, and your request for revision and recalculation of the regulatory review period is denied.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research